



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Group Art Unit 1644

In re

Patent Application of

Richard B. Mazess, et al.

Application No. 09/402,636

Confirmation No.: 6232

Filed: April 26, 2000

Examiner: Huynh, Phuong N.

"TARGETED THERAPEUTIC DELIVERY OF  
VITAMIN D COMPOUNDS"

I, Vicki Posekany, hereby certify that this correspondence is being deposited with the United States Postal Service in an envelope as "Express Mail Post Office to Addressee" mailing label number EV 086434063 US, addressed to Assistant Commissioner for Patents, Washington, D.C. 20231, on the date of my signature.

Vicki Posekany  
Signature

March 5, 2003

Date of Signature

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DECLARATION UNDER 37 C.F.R. §1.131

Assistant Commissioner for Patents  
Washington, DC 20231

Sir:

The undersigned hereby declare and state:

1. We are co-inventors of the subject matter of all the claims (i.e., pending claims 1-7, 9, 11, 17, 18, 20-22 and 41-48 as well as any newly added claims) of the above-identified U.S. patent application, as filed and as amended. We have assigned all rights, title, and interest in the above-cited invention to Bone Care International, Inc. ("Bone Care") This Declaration is submitted in furtherance of prosecution of the above-cited application.
2. All statements made herein based upon our own knowledge are true, and all statements made on information and belief are believed to be true.

3. This Declaration under 37 C.F.R. § 1.131 is, specifically, filed to antedate Kobayashi, et al. (Analytical Biochemistry 244: 374-383, Jan 1997), the printed publication date of which is January 15, 1997, and the effective publication date, i.e., date of receipt by the public is January 23, 1997.

4. Prior to January 15, 1997, we conceived the invention described in the subject application (referred to as file no. 017620-9277) and as defined in claims 1-7, 9, 11, 17, 18, 20-22 and 41-48 in this country, namely a method of targeted delivery for vitamin D compounds utilizing a conjugate that comprises a vitamin D moiety and a targeting molecule moiety.

5. We met with our patent attorney, Dr. Teresa Welch, and disclosed the invention in its various embodiments and authorized Dr. Welch to prepare a patent application.

6. Dr. Welch began preparing a provisional patent application, at least as early as September, 1996, describing our invention, as evidenced by invoices for her work from her law firm to our assignee, Bone Care.

7. On October 11, 1996, Dr. Welch forwarded a draft of the patent application with her cover memo (copy attached hereto as Exhibit A).

8. We worked diligently reviewing the application and returned it to our patent attorney with revisions, additions and/or corrections.

9. Our attorney worked diligently to review and revise the application which was filed February 13, 1997 and accorded U.S. Provisional Patent Application No. 60/038,364. The filing date of the provisional application is the priority date for the instant application.

10. Invoices from Stroud, Stroud, Willink, Thompson & Howard to the assignee of the subject application, Bone Care, dated from September, 11 1996 to February 13, 1997, are

attached hereto as Exhibits B, C, D and E, and describe the work of our patent attorney in preparing and filing the U.S. Provisional Patent Application No. 60/038,364.

11. All statements herein of our knowledge are true, all statements made on information and belief are believed to be true, and these statements are made with the knowledge that willful false statements and the like as made are punishable by fine or imprisonment or both under § 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: \_\_\_\_\_

Richard B. Mazess

Date: \_\_\_\_\_

Charles W. Bishop